Declaration - FDA

VEGAWAVE 63

Document ID: 36199

1 General information

Foodstuffs/Pharmaceutical

FDA stands for Food and Drug Administration, a U.S. authority. Among other things, this authority issues a regulation on the use of product-contacting materials in the pharmaceutical, food and beverage and cosmetics industries (Code of Federal Regulations CFR).

Regulation (EC) No. 1935/2004 of 27.10.2004 is aimed at ensuring a high level of protection of human health as well as the safety of comsumer articles and materials intended to come into contact with food.

The special focus of the regulation is on compliance with good manufacturing practice. We understand the principal aspect of good manufacturing practice to be making sure that parts with potential food contact are designed so that, at least under foreseeable conditions, the migration of constituent substances is largely avoided or does not occur in quantities that would endanger human health or bring about unacceptable changes in composition or organoleptic properties.

We meet these general requirements by purchasing parts and materials that will potentially come into contact with food with proof of compliance with FDA requirements or, in cases where there are no explicit FDA requirements, with a "No Objection Letter" from the Public Health Service of the Food and Drug Administration, or by obtaining the expert opinion of independent (accredited) laboratories and organizations in cases where uncertainties still exist.

Under the second aspect of good manufacturing practice we understand ensuring the traceability of components and products potentially coming into contact with foodstuffs throughout all stages of manufacturing and sales. This is guaranteed by our quality management system according to ISO 9001 und ISO 14001.

Generally use a suitable process seal meeting the product-specific requirements.

2 Manufacturer declaration

We hereby declare that the materials of the product-contacting parts of the following versions of VEGAWAVE 63 meet the requirements of the Food and Drug Administration.

Furthermore we confirm that the following versions of VEGAWAVE 63 fulfil the safety objectives of Regulation (EC) No. 1935/2004 of 27.10.2004.

Process fittings

Thread		
WE63.***GD****	WE63.***ND****	

Flange		
WE63.***2F****	WE63.***3F****	WE63.***AU****
WE63.***BU****	WE63.***CU****	WE63.***EF****
WE63.***EK****	WE63.***HA****	WE63.***HE****
WE63.***IA****	WE63.***JA****	WE63.***KF****
WE63.***MF****	WE63.***OA****	WE63.***OE****
WE63.***OF****	WE63.***PA****	WE63.***QF****
WE63.***SA****	WE63.***UA****	WE63.***ZF****

Clamp		
WE63.***CA****		

This declaration is based on the following certificates:

- Opinion letter of the Public Health Service of the Food and Drug Administration on the implemented stainless steels (College Park, MD 20740 of 22.11.2004)

Furthermore, it is the responsibility of the operator to ensure compliance with any additional food and process-specific requirements.

Note: This declaration is valid for instruments on which the document number "36199" is explicitly shown on the type label or the accompanying documentation.

Printing date:

All statements concerning scope of delivery, application, practical use and operating conditions of the sensors and processing systems correspond to the information available at the time of printing.
Subject to change without prior notice

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